CLAIMS:

1. A method for evaluation of a biological sample containing at least one cell type bearing at least one cellular target and at least one soluble analyte, the steps comprising:

(a) adding to a single container said sample with

(i) at least one soluble ligand that binds to said cellular target,

(ii) at least one soluble ligand that binds to said soluble analyte, or at least one competing soluble analyte; and

(iii) a solid phase capture medium that binds directly to said soluble analyte, indirectly to said soluble analyte, or to said soluble ligand that binds to said soluble analyte; and

(b) simultaneously analyzing said sample (a) without physically separating the complexes comprising a complex that forms between said cellular target and said at least one soluble ligand, and a complex that forms between said capture medium bound directly to said soluble analyte, or between said capture medium bound indirectly to said soluble analyte, or between said capture medium bound to said soluble ligand that is bound to said soluble analyte.

2. The method according to claim 1, wherein step (a) further comprises the steps:

(a1) adding to said sample a solid phase capture medium on which are immobilized multiple first ligands that are capable of binding to said soluble analyte, and wherein said capture medium, said first ligand, and said soluble analyte form a first complex;

(a2) adding to said sample of step (a1) a soluble second ligand that is capable of binding to said cellular target, wherein each second ligand is associated with a first detectable label, and wherein multiple second ligands can bind to a single target cell; wherein said second ligand and said cellular target form a second complex;

(a3) adding to said sample of step (a2) a third ligand that is capable of binding to said first complex, said third ligand associated with a second detectable label, wherein said third ligand and said first complex form a third complex; and

wherein step (b) comprises simultaneously analyzing said sample of step (a3) without physically separating said complexes by discriminating between said third complex and said second complex.

3. The method according to claim 1, wherein step (a) further comprises the steps:

(a1) adding to said sample (i) a known concentration of a first ligand associated with a first label, wherein multiple of said first ligands are capable of binding to a single said cellular target; and (ii) a known concentration of a second ligand associated with a second label, wherein said second ligand is capable of binding to said soluble analyte; and wherein said cellular target and said first labeled ligand form a first complex and said soluble analyte and said second labeled ligand form a second complex;

(a2) adding to said sample (a1) a solid phase capture medium on which are immobilized a known multiple of said analytes, and wherein said capture medium with immobilized analyte and any of said labeled second ligand not bound to said soluble analyte in said sample form a third complex; and

wherein step (b) comprises simultaneously analyzing said sample (a2) without physically separating said complexes by discriminating between said first complex and said third complex, wherein the amount of third complex detected is proportional to the amount of soluble analyte present in said sample.

4. The method according to claim 1, wherein step (a) further comprises the step:

(a1) adding to said sample (i) a known concentration of a first ligand associated with a first label, wherein multiple of said first ligands are capable of binding to a single said cellular target; and (ii) a known concentration of a competing soluble analyte associated with a second label, and (iii) a solid phase capture medium on which are immobilized a known multiple of second ligands capable of binding to said soluble analyte,

wherein said cellular target and said first labeled ligand form a first complex; wherein said labeled competing soluble analyte and said unlabeled soluble analyte in said sample compete for binding to said capture medium with immobilized second ligand, thereby forming a second complex wherein said capture medium is bound to

labeled competing analyte and a third complex wherein said capture medium is bound to unlabeled soluble analyte; and

wherein step (b) comprises simultaneously analyzing said sample (a1) without physically separating said complexes by discriminating between said first complex and said second complex, wherein the amount of second complex detected is proportional to the amount of unlabeled soluble analyte present in said sample.

5. The method according to claim 1, wherein step (a) further comprises the steps:

(a1) adding to said sample (i) a first ligand, wherein multiples of said first ligand are capable of binding to said cellular target and providing a first detectable signal; (ii) a second ligand, capable of binding to said soluble analyte and providing a second detectable signal; and (iii) a third ligand capable of binding to the same said soluble analyte; wherein said first cellular target and said first ligand form a first complex, wherein said soluble analyte bound to one or both of said second ligand and third ligand form a second complex;

(a2) adding to said sample (a1) a solid phase capture medium on which is immobilized multiple fourth ligands, said fourth ligands capable of binding to said second or third ligands, wherein said solid phase capture medium with immobilized fourth ligands, and said third ligands bound to a soluble analyte, which is bound to one or more second ligands form said third complex; and

wherein step (b) further comprises simultaneously analyzing said sample (a2) without physically separating said complexes by discriminating among said first complex, said second complex and said third complex.

6. The method according to claim 1, wherein said at least one soluble ligand (i) comprises multiple of the same ligand or different ligands.

7. The method according to claim 1, wherein said at least one soluble ligand (ii) comprises multiple of the same ligand or different ligands.

8. The method according to claim 1, wherein one or more of said ligands or competing soluble analyte is labeled with a detectable label or marker.

9. The method according to claim 8, wherein said label is a fluorescent compound.

10. The method according to claim 1, wherein said biological sample contains cells of biological tissue.

11. The method according to claim 10, wherein said biological sample is selected from the group consisting of whole blood, urine, synovial fluid, bone marrow, cerebrospinal fluid, vaginal mucus, cervical mucus, sputum, semen, amniotic fluid, any cell-containing exudates, cell-containing media, and cell-containing buffer.

12. The method according to claim 10, further comprising diluting said sample with saline, buffer or a physiologically acceptable diluent prior to the additional of soluble ligand.

13. The method according to claim 1, wherein said cell type is selected from the group consisting of red blood cells, white blood cells, granulocytes, macrophages, platelets, lymphocytes, lymphoblasts, blast cells, leukocytes, neutrophils, fibroblasts, dendritic cells, epithelial cells, epidermal cells, embryonic cells, hepatocytes, histiocytes, peritoneal cells, kidney cells, lung cells, sperm cells, oocytes, normal and cancer cells of other mammalian tissue, and mixtures thereof.

14. The method according to claim 1, wherein said cellular target is selected from the group consisting of a cell surface antigen, an intercellular antigen, nuclear antigen, a fragment thereof, and mixtures thereof.

15. The method according to claim 1, wherein said soluble analyte is selected from the group consisting of a serum marker, a protein, a virus, a hormone, a lipid, a nucleic acid sequence, a carbohydrate, a pharmaceutical drug, a toxin, and an antigen shed from a cell.

16. The method according to claim 1, wherein said capture medium is a physiologically compatible bead.

17. The method according to claim 16, wherein said bead is from 0.05 to 20 microns in diameter.

18. The method according to claim 15, wherein said capture medium is greater than 1μM in size.

19. The method according to claim 1, further comprising adding to said sample a reagent that inhibits phagocytosis of said capture medium without damaging said target cells or inhibiting binding to said target cells and said ligands.

20. The method according to claim 1, wherein each said ligand is independently selected from the group consisting of an antibody, an antigen, a nucleic acid sequence complementary to a target sequence, and an oligonucleotide sequence.

21. The method according to claim 1, further comprising washing said sample after combining said capture medium and said sample.

22. The method according to claim 1, wherein said sample contains blood cells, said method further comprising lysing said sample to remove red blood cells prior to said analyzing step.

23. The method according to claim 22, further comprising washing said sample after lysis.

24. The method according to claim 1, wherein said biological sample contains myeloid cells and wherein said method further comprises adding to said sample a reagent that inhibits phagocytosis of said capture medium by said myeloid cells.

25. The method according to claim 1, further comprising adding to said sample an inhibitor of cellular activation.

26. The method according to claim 25, further comprising adding the inhibitor of cellular activation with said sample prior to or simultaneously with the addition to the sample of said capture medium.

27. The method according to claim 26, wherein said inhibitor of cellular activation is selected from the group consisting of an anticoagulant, an inhibiting reagent, a fixative or an inhibiting reaction temperature below 25°C.

28. The method according to claim 1, wherein said method is useful in diagnosis of a disease or condition selected from the group consisting of sepsis, inflammation, autoimmune disease, cardiovascular disease, viral infection, bacterial infection, drug interaction.

29. The method according to claim 1, which is useful for evaluation of food or water for contamination with microorganisms or toxins.

30. A method for diagnosing sepsis or monitoring the progress thereof by performing the method of claim 1, wherein said cellular target is selected from the group consisting of CD64 (N), HLA-DR (Mo), CD11a, CD14/Cd16, CD142 (tissue factor); and said soluble target is selected from the group consisting of IL-6, IL-10, IL-1, TNF-alpha, neopterin, C-reactive protein, procalcitonin, Activated Protein C.

31. A method for diagnosing autoimmune disease or monitoring the progress thereof by performing the method of claim 1, wherein said cellular target is selected from the group consisting of activated T cells and activated B cells; and said soluble target is selected from the group consisting of C-reactive protein, a chemokine, and a cytokine.

32. A method for diagnosing cardiovascular disease or monitoring the progress thereof by performing the method of claim 1, wherein said cellular target is selected from the group consisting of platelet-leucocyte aggregates, CD142 (TF); and said soluble target is selected from the group consisting of hsC-reactive protein, troponin, and myoglobin.

33. A method for differential diagnosis of viral and bacterial infections or monitoring the progress thereof by performing the method of claim 1, wherein said cellular target is selected from the group consisting of HLA-DR, CD4/CD8, CD64(N), CD14/CD16; and said soluble target is selected from the group consisting of IFN-gamma, neopterin, and C-reactive protein.

34. A kit comprising:

(a) at least one soluble ligand that binds a cellular target in said sample;

(b) at least one soluble ligand that binds a soluble analyte in said sample or at least one soluble analyte associated with a detectable label; and

(c) a solid phase capture medium that binds directly to said soluble analyte, indirectly to said soluble analyte, or to said soluble ligand that binds to said soluble analyte.

35. The kit according to claim 34, further comprising a container comprising one or a mixture of components (a) through (c).

36. The kit according to claim 34, wherein said soluble ligand (a) is associated with a first detectable label; said solid phase capture medium (c) is associated with immobilized multiple first ligands that are capable of binding to said soluble analyte and wherein said capture medium-immobilized first ligand is capable of forming a first complex with said soluble analyte in a biological sample; and said soluble ligand (b) is associated with a second detectable label, and wherein said ligand (b) and said first complex are capable of forming a second complex.

37. The kit according to claim 34, wherein said ligand (a) is associated with a first label, wherein multiple of said ligand (a) are capable of binding to a single cellular target; said ligand (b) is associated with a second label; and wherein said solid phase capture medium (c) is associated with multiple of said soluble analytes.

38. The kit according to claim 34, wherein said ligand (a) is associated with a first label, wherein multiple of said ligand (a) are capable of binding to a single cellular target; said soluble analyte (b) is associated with a second label; and wherein said solid phase capture medium (c) is associated with multiple of said ligands capable of binding soluble analyte.

39. The kit according to claim 34, wherein said ligand (a) is associated with a first detectable marker; said at least one ligand (b) comprises a first ligand (b) associated with a second detectable marker and a second ligand (b); and said solid phase capture medium (c) comprises multiple immobilized ligands capable of binding to said first ligand (b) or second ligand (b).